IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GARY GILL, individually and on behalf of all others similarly situated, Plaintiff, v. BLUEBIRD BIO, INC., ANDREW OBENSHAIN, CHRISTOPHER KRAWTSCHUK, and RICHARD A. COLVIN, Defendants	**Case No. 1:24-cv-10803** **AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Larry Cattran ("Plaintiff"), individually and on behalf of all other persons similarly situated, by and through his undersigned attorneys, Complaint for violations of the federal securities laws based upon knowledge with respect to his own acts and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by bluebird bio, Inc. ("Blue" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Blue's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the Defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Blue's common stock between April 24, 2023 and December 8, 2023 (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws.

2. Blue is a biotechnology company that researches, develops, and commercializes gene therapies for severe genetic diseases. Its product candidates focus on severe genetic diseases including ZYNTEGLO ("betibeglogene autotemcel") for the treatment of transfusion-dependent ß-thalassemia; LYFGENIA ("lovotibeglogene autotemcel" or "lovo-cel") for the treatment of sickle cell disease ("SCD"); and SKYSONA ("elivaldogene autotemcel") to treat cerebral adrenoleukodystrophy.

3. On April 24, 2023, Defendants announced submission of its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for its lovo-cel gene therapy for patients with sickle cell disease ("SCD") ages 12 and older who have a history of vaso-occlusive events ("VOEs").[1] The BLA also included a request for priority review which, if granted, would reduce the FDA's review time for the application to six months from the time of filing, versus a standard review timeline of 10 months.

4. The FDA awards priority review vouchers ("PRV") to drug sponsors that develop drugs for tropical diseases or rare pediatric diseases or to use as medical countermeasures. A PRV can be extremely valuable and is critical in evaluating the profitability of a new product. The PRV—which can be sold to another drug sponsor—may be redeemed later to receive priority review from FDA with a targeted review time of 6 months, rather than the 10-month standard

[1] VOEs are a group of acute complications that are associate with SCD.

review, for a drug application of the PRV holder's choice. The purpose of a PRV is to incentive drug developers to develop drugs that may otherwise be less profitable due to the nature of the treatment and small market size.[2]

5. Leading up to the FDA's approval of lovo-cel, Defendants made multiple announcements which provided investors with false and misleading information made by Defendants with the intent of bolstering investor expectations and share prices. Specifically, Defendants created the false impression that: (i) they could obtain FDA approval for lovo-cel without any box warnings[3] for haematological malignancies; and (ii) they would be granted a priority review voucher by the FDA and in turn sell it in order to strengthen their financial position for the lovo-cel launch.

6. These public statements were materially false and misleading at all relevant times.

7. The Company significantly overstated Lyfgenia's clinical and/or commercial prospects, including its qualifications and ability to obtain a PRV and the likelihood and necessity of safety warnings on lovo-cel's label. Defendants intentionally and knowingly concealed and/or omitted pertinent information regarding these misstatements.

8. These misstatements caused Plaintiff and other shareholders to purchase Blue's securities at artificially inflated prices.

9. On December 8, 2023, Blue issued a press release announcing that it received approval from the FDA for its ex-vivo gene therapy drug Lyfgenia for sickle cell disease. Along with the approval came a black box warning for haematological malignancies with a requirement

[2] https://www.gao.gov/products/gao-20-251.

[3] Black box warnings, or boxed warnings, alert the public and health care providers to serious side effects, such as injury or death. The FDA requires drug companies to add a warning label to medications that have a black box warning.

to monitor patients for cancer through complete blood counts at least every six months for at least 15 years, plus viral vector integration site analysis at month 6, 12 and as warranted. Further, the Company's anticipated priority review voucher was denied by the FDA.

10. On this news, the price of Blue's common stock declined from a closing market price of $4.81 per share on December 7, 2023, to $2.86 per share on December 8, 2023.

11. Investors have sustained significant damages as a result of Defendants' fraudulent statements. Plaintiff seeks to recover those damages by way of this lawsuit.

JURISDICTION AND VENUE

12. Plaintiff brings this action on behalf of himself and other similarly situated investors to recover losses sustained in connection with Defendants' fraud.

13. The claims asserted herein arise under and pursuant to §§ 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b)and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

15. Venue is proper in this District pursuant to § 27 of the Exchange Act and 28 U.S.C. § 1391(b), as Defendant Blue is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

16. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

17. Plaintiff purchased Blue common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Blue is attached hereto. *Exhibit 1*, Certificate of Investment.

18. Blue is a Delaware corporation with its principal executive offices located at 455 Grand Union Boulevard, Somerville, MA 02145. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "BLUE."

19. Defendant Andrew Obenshain ("Obenshain") was, at all relevant times, the President, Chief Executive Officer ("CEO"), and a Director of Blue. As President, CEO, and Director of Blue, Defendant Obenshain was actively involved in press releases and investment calls, as well as staying informed on Blue's production and testing of lovo-cel and FDA application. As President, CEO, and Director of Blue, Defendant Obenshain is charged with knowledge of major corporate decisions and announcements – including information regarding the development of lovo-cel, the likelihood of lovo-cel being granted PRV and getting approval without a black box warning, and all announcements regarding such.

20. Defendant Christopher Krawtschuk ("Krawtschuk") was, at all relevant times, the Chief Financial Officer ("CFO") of Blue. As CFO of Blue, Defendant Krawtschuk was actively involved in press releases and investment calls, as well as staying informed on Blue's production and testing of lovo-cel and FDA application. As CFO of Blue, Defendant Krawtschuk is charged with knowledge of Blue's financial status and decisions – including information regarding the development of lovo-cel, the likelihood of lovo-cel being granted PRV and getting approval

without a black box warning, and all announcements regarding such as such announcements were intended to raise funds and investor interest.

21. Defendant Richard A. Colvin ("Colvin") was, at all relevant times, the Chief Medical Officer ("CMO") of Blue. As CMO of Blue, Defendant Colvin was involved overseeing the production and testing of lovo-cel, directing the lovo-cel FDA application process, and communicating with the FDA throughout the process. As CMO of Blue, Defendant Colvin is charged with knowledge of the development and testing of new products such as lovo-cel including the likelihood of lovo-cel being granted PRV and getting approval without a black box warning, and all announcements regarding such.

22. Defendants Obenshain, Krawtschuk, and Colvin are collectively referred to herein as the "Individual Defendants."

23. Blue together with the Individual Defendants are referred to herein as the "Defendants."

24. The Individual Defendants, because of their positions with the Company, possessed and exercised the power and authority to control the contents of Blue's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. It is believed that each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants

are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

25. Blue is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful act complained of herein were carried out within the scope of their employment with authorization.

26. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Blue under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

A. Company Background

27. Blue is a biotechnology company that researches, develops, and commercializes gene therapies for severe genetic diseases, including ZYNTEGLO for the treatment of transfusion-dependent ß-thalassemia, LYFGENIA ("lovo-cel") for the treatment of sickle cell disease, and SKYSONA to treat cerebral adrenoleukodystrophy.

28. In past years, Blue experienced cash flow issues.

29. According to one of Blue's former employees, a Senior Director in Enterprise Data Management (IT) from 2018 through October 2023 ("CW#1"), Blue announced internally to its employees, including CW#1, that the Company needed to raise or bring in additional money as of June 2023. At that point, Blue would need a cash infusion and only had enough money to continue operations through February 1, 2024. CW#1 learned this information directly from the Company during her time as an employee at Blue.

30. Blue's cash flow problems and problematic revenue issues were known by each of the Individual Defendants due in part to limited manufacturing and European countries not willing to pay the high price for the treatment provided by Blue.

31. In late 2021 or early 2022, the Company knew its treatments were not making progress or being accepted in Europe. During this timeframe, the Company did not get the payment it had anticipated from the German government. Because of this, Blue closed its operations in Europe, where it had been operating out of Zug, Switzerland. In Europe, a significant amount of health care is government based or paid directly by the governments. As such, the government authorities set payment schedules. Blue wanted $2 million for Zynteglo treatment per patient, but the German access pricing team did not value the treatment at $2 million and did not approve the higher amount demanded by Blue.

32. Even after receiving FDA approval for Zynteglo in August 2022, Blue only had the capacity to treat one patient per week, limiting Blue's potential revenue from Zynteglo.

33. Rather than investing more money in the research and development of new, more effective drugs, Blue began using the information, processes, and technology from their prior drugs to create nearly identical drugs to cure different diseases, including lovo-cel, in order to increase profits.

34. Defendants intentionally ignored the risks associated with their "new" drug, lovo-cel, and began to push their stale technology, over exaggerating the likely market share and profitability of lovo-cel.

35. Similar to Zynteglo, lovo-cel was also valued at $2 million and revenue could only be recognized when a patient was infused. Lovo-cel was merely Zynteglo repackaged to treat a new disease and bring in additional revenue. Based on this information, Defendants knew or should have known that lovo-cel bring the same revenue challenges that the Company has experienced with Zynteglo. In order to raise much needed funds, Defendants overstated lovo-cel's abilities.

36. According to one of Blue's former employees, a Senior Associate Scientist employed by Blue from May 2022 through March 2024 ("CW#2"), as Blue began developing lovo-cel, Defendants knew that its direct competitor Vertex was developing Casgevy, a competing but more advanced product. Blue wanted to be first to bring the product to the market, noting that hospitals generally tend to select just one supplier. CW#2 learned this information during his time as an employee at Blue.

37. Lovo-cel is a second-generation viral vector therapy, whereas Vertex's drug is a third-generation therapy. Essentially, as Defendants knew, Vertex's drug is a better, more advanced product at a lower price point than lovo-cel.

38. Lovo-cel uses a lentiviral vector based upon the HIV virus. Lovo-cel focuses on clearing out the defective bone marrow and replacing it with stem cells which the body will then propagate. It is designed to be a one-time therapy.

39. As Defendants understood, the problem with the lentiviral vector technique is that it is far more likely to produce off-target mutations, including potentially cancer. Medical providers have no control over the drug once it has entered a person's system.

40. On the other hand, Casgevy was created from bacteria in yogurt which could enter other life forms and change the DNA. It strategically alters a small part of someone's DNA. The technology involved using a protein which can be placed into the DNA and put in new DNA. As Defendants knew, this is far more novel and efficient than using a virus.

41. Lovo-cel was hardly a new drug, like Casgevy, but rather an older generation drug that Blue was using to attempt to cure a different disease.

42. Despite this, Defendants promised investors that lovo-cel would be granted a priority review voucher – a devised used to incentive new drug production.

43. Defendants further ignored the casualties and risks associated with lovo-cel and failed to inform investors and/or intentionally mislead investors into believing that lovo-cel would be approved without a black box warning.

44. Defendants focused on competing with Vertex's upcoming drug, Casgevy, and generating new revenue sources for Blue, to the detriment of its investors. This led to Defendants' materially false and misleading statements at issue in this case.

B. Materially False and Misleading Statements Issued During the Class Period

45. On April 24, 2023, Blue issued a press release announcing it was submitting a Biologics License Application to the FDA for lovo-cel gene therapy in patients with sickle cell disease ("SCD") ages 12 and older who have a history of vaso-occlusive events ("VOEs"). The press release stated in pertinent part:

> The BLA includes a request for Priority Review, which, if granted, would shorten the FDA's review of the application to six months from the time of filing, versus a standard review timeline of 10 months. If approved, lovo-cel will be bluebird bio's third ex-vivo gene therapy approved by the FDA for a rare genetic disease and its second FDA approval for an inherited hemoglobin disorder, building on more than a decade of leadership in gene therapy.
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> "The severity of sickle cell disease, and its impact on patients and caregivers, has been underappreciated and overlooked for far too long. Transformative therapies for this community are long overdue," said Andrew Obenshain, chief executive officer, bluebird bio. "We are pleased to have satisfied the Agency's questions about comparability to enable our BLA submission, and to take this important step toward making lovo-cel available for individuals living with SCD."
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> Lovo-cel is the most deeply studied gene therapy in development for sickle cell disease. The BLA submission is based on efficacy results from 36 patients in the HGB-206 Group C cohort with a median 32 months of follow-up and two patients in the HGB-210 study with 18 months of follow-up each. The BLA submission also includes safety data from 50 patients treated across the entire lovo-cel program, including six patients with six or more years of follow-up.
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> The FDA previously granted lovo-cel orphan drug designation, fast track designation, regenerative medicine advanced therapy (RMAT) designation, and rare pediatric disease designation for the treatment of SCD.

46. The Individual Defendants, as CEO, CFO, and CMO of Blue, had knowledge of this press releases and the information contained therein. In their roles as CEO, CFO, and CMO (*i.e.*, "Control Persons"), Individual Defendants had the authority and responsibility to approve such press releases, and the accuracy of the information contained therein. In fact, the press release contains statements from CEO, Defendant Obenshain.

47. The Individual Defendants approved this press release, either expressly or impliedly through their actions by allowing the information to be released to the media without altering or retracting any statements.

48. During the Bank of America Annual Healthcare Conference held on May 11, 2023, Defendants were asked about the lovo-cel submission, expectation of a priority review and an Ad Comm meeting. Defendant Obenshain stated in pertinent part:

> <Q: Jason Matthew Gerberry -Bank of America Securities Research Division – Managing Director> Okay, so the big update was obviously lovo-cel and getting the submission in. And maybe it seems like a no-brainer, you'll get priority review, but just your level of confidence that you'll be able to get prior to your review with that.
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> <A: Andrew Obenshain> Well, certainly, that's always up to the FDA, but we do have all the designations. We have the indication for it. So we do believe that we will get that priority review.
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> * * *
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> <Q: Jason Matthew Gerberry -Bank of America Securities Research Division – Managing Director> Got it, okay. The regulatory process, I presume there's going to be an AdCom. Any specific elements of the label that you feel like are important one way or another in terms of being market limiting or giving you more latitude to operate in the space.
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> <A: Andrew Obenshain> So we do anticipate that there will be an AdCom for us with the FDA, but we are prepared for that. In fact, we've done 2 of them successfully in the past. So I think we think we're pretty good at them. So we'd actually welcome that opportunity. In terms of the label, I don't think there's any one particular area that the FDA would focus on overall. I think the -- if we look

> back at our ZYNTEGLO AdCom, it was the efficacy and safety, which is pretty standard. So I don't think there's any one element that they're going to actually hold in on versus others.

49. Upon information and belief, Defendant Obenshain's statements were made at the direction of, approved by, and based on information received from CFO Defendant Krawtschuk, and CMO Defendant Colvin.

50. During a second quarter 2023 earnings call held on August 8, 2023, Individual Defendants (as active participants on the call) were questioned about expectations for the lovo-cel label as well as if the FDA will grant a priority review voucher.

> <Q: Luca Issi -RBC Capital Markets, Research Division – Analyst> Just 2 quick one here. Maybe on sickle cell disease. What are your expectations for the label? In particular, do you anticipate that the label will include patients between 12 and 18 years of age? The reason why I'm asking, I believe your competitor does not have patients in that subgroup for the primary efficacy set, at least from the data at EHA. So wondering if it's plausible that you'll get a broader label than your competitor? And if so, what are the implications for the launch?
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> And then maybe for the runway, can you just remind me if you do get approved for sickle cell disease, will you receive the PRV? And if so, are you planning to monetize it?
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> * * *
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> <A: Richard A. Colvin> Yes, we submitted the BLA for the treatment of patients who are between 12 and 18 and over in that matter. We included patients between 12 and 18, both in our study, HGB-206 Group C as well as in study 210. So for that reason, we have patients who are in that age range and have seen the results from those patients. And I'll turn it back over to Chris.
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> <A: Christopher Krawtschuk> As it relates to the PRV and given Rich's comments, it's possible we could receive a PRV since lovo-cel BLA was accepted for priority review for patients 12 and over. However, as it relates to whether or not we'd monetize it, we of course, would look at the market, evaluate the opportunities in the market and then make a decision based upon what we see there. I don't want to comment today on whether or not -- we monetize it or not until we know whether or not we get a fair price for it. And just as a reminder, the PRV is not factored. Any potential PRV is not factored into our cash runway.

51. Upon information and belief, Defendant Krawtschuk's statements were made at the direction of, approved by, and based on information received from CEO Defendant Obenshain, and CMO Defendant Colvin.

52. Later, during the Company's third quarter 2023 earnings call held on November 7, 2023, Defendant Obenshain discussed the much-anticipated launch of lovo-cel and the lack of an Ad Com meeting by the FDA. He stated in pertinent part:

> …I'm excited today to update you on bluebird's Q3 results and our preparations for the potential upcoming FDA approval of lovo-cel. This has been a transformative year for the field of gene therapy and for bluebird bio. We validated the commercial model for gene therapy with our ZYNTEGLO and SKYSONA launches. And as a reminder, bluebird occupies a unique strategic position as one of the only standalone commercial gene and cell therapy companies with an extensive platform of gene therapy expertise that will potentially enable growth, profitability, and expansion for years to come. And we are in an incredibly exciting moment for our company, but most importantly for patients as we approach the potential FDA approval of lovo-cel for sickle cell disease in December.
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> * * *
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> We believe the fact that the FDA Advisory Committee wasn't requested for lovo-cel is a testament to the breadth and the depth of the lovo-cel data significantly more than any other gene therapy program for sickle cell disease. Additionally, this is the third lentiviral vector gene therapy that the FDA has reviewed from bluebird and thus, a technology they are very familiar with. Our lentiviral vector technology is also uniquely traceable, giving us an unrivaled understanding of our therapies and the ability to conduct a rigorous monitoring. We understand it can measure how we modify the cell to monitor effects over time. Last week, we announced that in early December, we will be presenting long-term follow-up data from our ZYNTEGLO and lovo-cel programs at the 65th ASH Annual Meeting with an unparalleled up to 9 years of follow-up in transfusion-dependent beta-thalassemia and 5 years of follow-up in our sickle cell disease program.
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> We continue to progress plans for our anticipated lovo-cel commercial launch in early 2024, following its potential FDA approval.

53. Upon information and belief, Defendant Obenshain's statements were made at the direction of, approved by, and based on information received from CFO Defendant Krawtschuk, and CMO Defendant Colvin.

54. On the same earnings call, Defendant Krawtschuk reiterated that Blue had entered into an advanced agreement to sell the priority review voucher which the Company expected to be granted by the FDA. He stated in pertinent part:

> …We remain on track with our full-year 2023 cash burn guidance in the range of $270 million to $300 million and continue to prudently deploy capital to bring our therapies to our patients. Additionally, last week, we announced that we've entered into an advanced agreement to sell a priority review voucher, if granted, for lovo-cel for sickle cell disease for $103 million. This would be an important source of non-dilutive capital and has the potential to strengthen our financial position ahead of the anticipated launch of lovo-cel.
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> As of September 30, we had $227 million in cash, cash equivalents, restricted cash, and marketable securities, not including the potential proceeds from the PRV sale or the release of our $53 million in restricted cash, we have a cash runway into Q2 of next year. We plan to provide an updated cash runway guidance by early 2024 and continue to explore additional financing opportunities to further extend our cash runway.

55. Upon information and belief, Defendant Krawtschuk's statements were made at the direction of, approved by, and based on information received from CEO, Defendant Obenshain, and CMO, Defendant Colvin.

56. More significantly, during the question and answer segment of the call, Individual Defendants (as active participants on the call) were asked about the status of the labeling stage for lovo-cel and if there would be any mention of safety events.

> <Q: Yanan Zhu -Wells Fargo Securities, LLC Research Division – Analyst> …First, could you talk about whether for the BLA or lovo-cel, whether you're in the labeling discussion stage with the FDA?
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> <A: Andrew Obenshain> Yes. So on the BLA, we don't comment on ongoing interactions with the agency. So we've submitted for the lovo-cel the treatment of patients with sickle cell disease is 12 and older who have a history of vaso-occlusive events, and we are confident in the robustness and maturity of our BLA package and the review process.

* * *

> <Q: Luca Issi -RBC Capital Markets, Research Division – Analyst> …And then maybe on safety. Any update on the 2 patients that develop AML in the trial for sickle cell disease? Wondering if you could comment on how they're doing today and maybe bigger picture, whether there is a scenario where you get a label that includes risk of secondary malignancies while your competitor does not? And if that's a scenario, how should we think about implications for the launch?
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> <A: Thomas J. Klima> Sure. Yes, we're going to run the same process on our price for lovo-cel that we ran with ZYNTEGLO and SKYSONA. Obviously, different dynamics in sickle cell disease. But we'll take it into consideration the clinical benefit, quality of life improvements, cost-savings system, impact to society, just like we do with our other therapies, obviously a one-time potentially curative therapy in a chronic condition. Many are seeing the values recognized by payers as recognized recently by ICER. So clearly, the models are out there. But we won't comment on our competitors' pricing. We don't obviously have any privy to that. We believe that we are leaders in establishing value and setting price for these therapies, and we will continue to price the way that we price.
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> <A: Andrew Obenshain> ***And then, Luca, just on the safety issues. As a reminder, there have been no cases of insertional oncogenesis with lovo-cel. However, there have been cases of cancer related to the transplant procedure involving lovo-cel. And unfortunately, 2 of those patients in our early clinical trials where we -- our procedures were in the earlier phase of Generation 1 procedure since the Group A did develop leukemia and AML, and those 2 patients did pass away. So although they are not -- those 2 patients are not in our efficacy data set, it is likely that we will have a mention of that in the safety events in the label. In what part of the label or where is yet to be determined, but certainly, they will be in there. That's something that we've known for quite a while.***
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> ***Again, I think the really important point is there are no cases of insertional oncogenesis. And so these are cases that were related to the procedure.***

(Emphasis added.)

57. Upon information and belief, Defendant Obenshain's statements were made at the direction of, approved by, and based on information received from CFO, Defendant Krawtschuk, and CMO, Defendant Colvin.

58. The above statements in Paragraphs 45 to 57 were materially false and/or misleading. Specifically, Defendants knowingly created the false impression that: (i) they could obtain FDA approval for lovo-cel without any black box warnings for haematological

malignancies, and (ii) they would be granted a priority review voucher by the FDA and in turn sell it in order to strengthen their financial position for the lovo-cel launch. As a result, the Company had significantly overstated Lyfgenia's clinical and/or commercial prospects. Therefore, the Company's public statements were materially false and misleading at all relevant times.

59. At all relevant times, Defendants knew or should have known that lovo-cel would be issued a black box warning.

60. The purpose of a black box warning is to inform the public of a known risk associated with a drug.

61. It is extremely difficult and rare for a gene therapy to be approved without a black box warning. Almost every gene therapy approved by the FDA has come with a black box warning because gene therapy treatments are inherently dangerous.

62. According to a former Blue employee, a Regulatory Affairs Consultant for Blue from late 2022 through late 2023 (CW#3), Blue experienced difficulties in trying to prove to the FDA that the drug worked and to show that the drug did not cause a more fatal disease than the underlying disease the patient already had. The aplastic anemia that occurred in the clinical trials that led to the black box warning, was because of a patient death. CW#3 learned of this information from her position at Blue.

63. The safety data included in the BLA for lovo-cel included 50 patients treated across multiple clinical trials; 6 of these patients had at least 6 years of follow-up. The serious adverse events ("AEs") related to lovo-cel in this dataset included cases of anemia in 2 patients with alpha-thalassemia and leukemia (not resulting from insertional oncogenesis) in 2 patients. Nonserious AEs related to lovo-cel in this dataset include cases of infusion reactions, namely hot flush and

decreased blood pressure, in 2 patients. Three of the 50 patients included in the BLA submission's dataset have died: 1 patient died from sudden cardiac death and 2 patients died from leukemia.

64. As CMO, Defendant Colvin was familiar with and understood the ramifications of these test results. Defendant Colvin had a duty to inform the CFO, Defendant Krawtschuk, and CEO, Defendant Obenshain of this information, and did inform Defendant Krawtschuk and Defendant Obenshain of this information, as it directly related to lovo-cel's ability to receive FDA approval without a black box warning.

65. Based on their own clinical trials, Defendants knew that there was potential for cancer and/or death with lovo-cel. Hence, Defendants knew or should have known that blood monitoring or some sort of black box warning would be mandated with the lovo-cel.

66. However, Defendants intentionally or recklessly ignored the extreme side effects and risks associated with the lovo-cel and misled investors to believe that lovo-cel would be approved without a black box warning. Rather, Defendants intentionally downplayed the associated risks and told investors that risks would only be included on the safety events on the label.

67. Defendants intentionally withheld the material information regarding causation and connection between the lovo-cel treatment and leukemia. Defendants' announcement intentionally led investors to believe that there was sufficient evidence to believe that lovo-cel did not cause leukemia – *i.e.*, only a safety event on the label would be appropriate. However, Blue did not have sufficient information and data to make such statements and disprove a connection between lovo-cel and leukemia.

68. Safety events on a label differ greatly from a black box warning.

69. Medications with boxed warnings associated with them may have adverse financial consequences as these warnings can affect the marketability of the drug and generate negative news reports. Safety events on a label are not nearly as prominent and do not have the same adverse financial consequences as a box warning.

70. Moreover, lovo-cel's black box warning requires consistent monitoring – further affecting lovo-cel's profitability.

71. At all relevant times, Defendants knew or should have known that lovo-cel would not be granted a PRV.

72. Defendants were not justified in relying on their prior FDA approvals for lovo-cel. Rather, Defendants knew that lovo-cel was not a new drug which warranted a PRV.

73. PRVs and qualifications therefore are governed by the Federal Food, Drug and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 9, *et seq*. Pursuant to 21 U.S.C. § 360ff(a)(4), a rare pediatric drug may qualify for a PRV, if the drug "contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the Public Health Service Act [42 U.S.C. 262(a), 262(k)]."

74. At all relevant times, Defendants knew or should have known of this readily available, public information.

75. Blue had told the FDA that it developed a new drug to cure a disease. However, Blue's "new drug," lovo-cel was hardly new. Rather, lovo-cel came from stale technology and contained an active ingredient that had already been previously approved in another PRV.

76. Defendants knew that lovo-cel contained an active ingredient that had already been previously approved in Blue's Zynteglo PRV. Defendants were merely repackaging an old drug and attempting to double dip – which is expressly prohibited under statute. Defendants did not take

on the same level of risk in developing this drug as they did the prior drug. As such, Defendants had no reasonable foundation to believe that they would be able to reuse their stale technology and receive PRV for lovo-cel.

77. Defendants understood that the purpose of a PRV is to incentive the creation of less-profitable drugs. Defendants knew that they were not giving the FDA a new drug, but a repackage drug that had already been developed and given a PRV in its prior development. Defendants had no reason to believe that this repackaged drug would be given another incentive based on the clear governing law prohibiting such.

C. The Truth Emerges

78. On December 8, 2023, Blue issued a press release announcing that it received approval from the FDA for its ex-vivo gene therapy drug Lyfgenia for sickle cell disease. However, the FDA approval also came with a black box warning for haematological malignancies and requirement to monitor patients for cancer through complete blood counts at least every six months for at least 15 years. Further, the Company's anticipated priority review voucher was denied by the FDA. The press release stated in pertinent part:

> bluebird bio, Inc. (Nasdaq: BLUE) ("bluebird bio" or "bluebird") today announced the U.S. Food and Drug Administration (FDA) has approved LYFGENIA™ (pronounced as 'lif-JEN-ee-uh') (lovotibeglogene autotemcel), also known as lovo-cel, for the treatment of sickle cell disease in patients ages 12 and older who have a history of vaso-occlusive events (VOEs). LYFGENIA is a one-time gene therapy that has the potential to resolve vaso-occlusive events and is custom-designed to treat the underlying cause of sickle cell disease.
>
> "Bringing LYFGENIA to people living with sickle cell disease is a milestone that bluebird has been working toward for almost a decade—and one that members of the sickle cell disease community have been waiting on for much longer," said Andrew Obenshain, chief executive officer, bluebird bio. "LYFGENIA has the potential to have a transformational impact for patients who currently live under the shadow of unpredictable and debilitating vaso-occlusive events. This approval also marks bluebird's third *ex vivo* gene therapy approved by the FDA for a rare cementing our position as a gene therapy leader."

"We're enthusiastic at the Sickle Cell Disease Association of America Inc. about the FDA's approval of this therapy, which could change the lives of people and families affected by sickle cell disease," said Regina Hartfield, president and CEO of the Sickle Cell Disease Association of America Inc. "As the national advocacy organization for people with sickle cell, we're strongly supportive of the new potentially curative option for treatment and excited for the future."

"People living with sickle cell disease face potentially devastating health consequences, diminished quality of life, and harmful stigma as a result of their disease," said Julie Kanter, M.D., a LYFGENIA investigator and director of the University of Alabama Birmingham Adult Sickle Cell Clinic and associate professor in the Division of Hematology and Oncology. "Today we can celebrate the availability of a potentially transformative new therapeutic option made possible by the incredible courage of patients and families who participated in clinical studies."

* * *

LYFGENIA was granted Priority Review in June 2023. ***The Company did not receive a Rare Pediatric Disease Priority Review Voucher as part of the review.*** LYFGENIA was previously granted orphan drug designation, fast track designation, regenerative medicine advanced therapy (RMAT) designation, and rare pediatric disease designation.

Clinical Data Supporting Approval of LYFGENIA The FDA approval of LYFGENIA builds on decades of research into lentiviral vector gene addition therapy and the largest clinical development program of any gene therapy for sickle cell disease.

The label is based on data from patients from the Phase 1/2 HGB-206 study. Safety data supporting the application includes data from 54 patients who initiated stem cell collection. Efficacy for LYFGENIA was supported by data from 36 patients in the Phase 1/2 HGB-206 Group C study following enhancements to the treatment and manufacturing processes made through the course of the clinical development program. 32 patients were evaluable for the endpoints of complete resolution of VOEs and severe VOEs in the 6-18 months post-infusion including 8 adolescent patients. In this cohort:

• Severe vaso-occlusive events were resolved in 30/32 patients (94%)
• 28/32 patients (88.2%) experienced no vaso-occlusive events at all

In the studies, VOEs are defined as episodes of acute pain with no medically determined cause other than a vaso-occlusion, lasting more than two hours and severe enough to require care at a medical facility. This includes acute chest syndrome requiring oxygen treatment and/or blood transfusion, acute hepatic

> sequestration, acute priapism lasting 2 hours and requiring care at a medical facility and acute splenic sequestration. sVOEs require a 24-hour hospital stay or emergency room visit, or at least two visits to a hospital or emergency room over a 72-hour period, with both visits requiring intravenous treatment; all VOEs of priapism are also considered sVOEs.
>
> The most common adverse reactions ≥ Grade 3 (incidence ≥ 20%) were stomatitis, thrombocytopenia, neutropenia, febrile neutropenia, anemia, and leukopenia. ***As previously reported, three patients died during LYFGENIA clinical trials; one from sudden cardiac death due to underlying disease and two from acute myeloid leukemia who were treated with an earlier version of LYFGENIA using a different manufacturing process and transplant procedure. Please see LYFGENIA Important Safety Information below, including a Boxed Warning for Hematologic Malignancy.***
>
> ***Patients treated with LYFGENIA in bluebird bio-sponsored clinical studies will be monitored for a total of 15 years through a long-term safety and efficacy follow-up study (LTF-307).***

(Emphasis added.)

79. On the same day, the FDA also approved Vertex's drug Casgevy for the treatment of sickle cell disease in patients 12 years and older. However, Casgevy's approval came with a priority review voucher and did not come with a black box warning.

80. Hematologic malignancy has occurred in patients treated with lovo-cel, and as such, a black box warning is included in the label for the therapy with information regarding this risk. The FDA noted that patients receiving lovo-cel should have lifelong monitoring for these malignancies.

81. On an earnings call the same day, the Individual Defendants (as active participants on the call) were questioned as to the presence of a box warning on Lyfgenia's label.

> <Q: Eric William Joseph – JP Morgan Chase & Co, Research Division – Analyst> Congrats for the approval. Do you expect the presence of a box warning to, I guess, have an impression? Or how do you expect physicians to receive the presence of a box warning with LYFGENIA relative to Casgevy? Not only physician impressions, but also impressions by QTCs. Did you test for sort of physician market perception around box warning in your market research? Do you expect it to have an impact on sort of pricing negotiations with payers?

> <A: Richard A. Colvin> Yes. Thanks, Andrew, and thanks, Eric. And so as we've reported before, hematologic malignancy has occurred in patients who receive LYFGENIA in clinical studies. This is an important risk that all patients must be aware of, counseled on and -- if they're considering getting gene therapy.
>
> One thing to remember, though, that's very important is that there have been no cases of insertional oncogenesis that have been observed and that this risk of this type of malignancy is not unique to LYFGENIA. The AML case that occurred in our studies used a process to manufacture the cells that we no longer use. And we characterize it very carefully in the medical and scientific literature. And we've talked about it with the physician community, the QTC community, and we published it in the New England Journal of Medicine.
>
> In fact, what we've learned from our program have informed not only the development program for LYFGENIA, but the broader gene therapy field, especially in sickle cell disease. ***The potential for a box warning was something we anticipated and it was built into our commercial projections.***

(Emphasis added.)

82. The aforementioned press release and statements made by the Individual Defendants were misleading and in direct contrast to statements made in their November 7, 2023 earnings call. On that call, Defendant Obenshain discussed the possibility of a "mention" in the safety events of the label regarding the two patients who developed AML and later passed away in the earlier clinical trials. Yet, there was no indication by any of the Defendants of a possibility of a black box warning which is the most prominent type of warning on a drug label. Further, the boxed warning is not just a safety deterrent. It comes with a requirement to "monitor patients for cancer through complete blood counts at least every six months for at least 15 years, plus viral vector integration site analysis at month 6, 12 and as warranted."

83. An analyst at J.P. Morgan lowered its price target reporting that "…While Lyfgenia's early approval is a welcome upside surprise (original PDUFA date Dec 20), the inclusion of a black box warning for hematological malignancies and the absent pairing of a priority review voucher arrives short of expectations. Of note, we do not see the inclusion of a

black box warning impeding the overall competitiveness of Lyfgenia; however, we concede that it is unexpected give the lack of adcom during the review cycle . . . .”

84. In denying Blue’s PRV request, the FDA stated:

> Your request for a rare pediatric disease priority review voucher has been denied. Although your biological product has a rare pediatric disease designation, you did not qualify for the voucher because your application did not meet the requirements to be a “rare pediatric disease product application” under section 529(a)(4) of the Federal Food, Drug & Cosmetic Act (FD&C Act) for the following reason:
>
> FDA has determined that BLA 125788 is not a human drug application for a biological product that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the PHS Act. Specifically, BLA 125788 is for a biological product that contains an active ingredient that was previously approved in another application under section 351(a) of the PHS Act. The active ingredient was previously approved, on August 17, 2022, in BLA 125717 for Zynteglo (betibeglogene autotemcel).[4]

85. An analyst with Cantor Fitzgerald commented on lack of priority review voucher stating “. . . we speculate that because BLUE already received a PRV on Zynteglo, a closely related therapy for beta thalassemia, the FDA may have viewed BLUE’s request as double-dipping . . . .” The analyst also noted that Lyfgenia users would require additional monitoring stating “. . . Monitoring includes a blood assessment every six months for 15 years, a requirement not present for Casgevy. Patients are thus likely to prefer Casgevy when given an option, as these therapies are “one and done.”

86. As a result, investors and analysts reacted immediately to Blue’s revelation. The price of Blue’s common stock declined dramatically. On this news, the price of Blue’s common stock declined from a closing market price of $4.81 per share on December 7, 2023, to $2.86 per share on December 8, 2023.

[4] FDA U.S. Food & Drug Administration, BLA Approval (Dec. 8, 2023), available at https://www.fda.gov/media/174617/download?attachment.

87. Defendants intentionally mislead Plaintiffs and the Class Members in order to increase investments and cash flow.

88. Prior to Defendants' December 8, 2023 announcements, Plaintiff and the Class Members had no way of knowing that lovo-cel was the cause of death for the three patients in Blue's trials. The test results of lovo-cel and information regarding the cause of death for the three patients was withheld from the public.

89. Plaintiff and the Class Members had no reasonable method to learn of Defendants' omissions or otherwise discover that their statements regarding the black box warning were misleading. Rather, Plaintiff and the Class Members justifiably relied on Defendants' misstatements and omissions, suggesting that lovo-cel would not be issued a black box warning and only a safety event on the label would be required.

90. Prior to Defendants' December 8, 2023 announcements, Plaintiff and the Class Members had no way of knowing that lovo-cel did not qualify for a PRV because an active ingredient had already been previously approved in Blue's Zynteglo PRV. Lovo-cel's medical makeup was not made known to the public.

91. Plaintiff and the Class Members had no reasonable method to learn of Defendants' omissions or otherwise discover that their statements regarding the PRV were misleading. Rather, Plaintiff and the Class Members justifiably relied on Defendants' misstatements as to the high likelihood/certainty that lovo-cel would be issued a PRV.

D. Loss Causation and Economic Loss

92. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Blue's common stock, or maintained levels of artificial inflation in

Blue's common stock price, and operated as a fraud or deceit on Class Period purchasers of Blue's common stock by materially misleading the investing public. Later, when Blue and Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Blue's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Blue's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

93. Blue's stock price fell in response to the corrective event on December 8, 2023, as alleged *supra*. On December 8, 2023, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Blue's approval by the FDA for its drug Lyfgenia free of any black box warnings and granting of a priority review voucher.

E. Presumption of Reliance; Fraud-On-The-Market

94. At all relevant times, the market for Blue's common stock was an efficient market for the following reasons, among others:

a. Blue's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

b. Blue communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

c. Blue was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain

customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

d. Unexpected material news about Blue was reflected in and incorporated into the Company's stock price during the Class Period.

95. As a result of the foregoing, the market for Blue's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Blue's stock price. Under these circumstances, all purchasers of Blue's common stock during the Class Period suffered similar injury though their purchase of Blue's common stock at artificially inflated prices, and a presumption of reliance applies.

96. Alternatively, reliance need not be proven in this action because the action involves omission and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affilated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts be withheld by material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

F. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

97. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors statements about the safety, labeling, and/or regulatory exposure concerning Blue's products while at the same time omitting material adverse information regarding the same that existed and was in their possession at the time of their alleged false statements.

98. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purported forward-looking statements.

99. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Blue who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

100. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Blue's common stock during the Class Period (the "Class").

101. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a

controlling interest, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members.

102. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Blue's common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Blue or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice like that customarily used in securities class actions. As of November 3, 2023, there were 109 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable. During the Class Period, the average daily trading volume of shares was approximately 6,695,700.

103. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

104. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

105. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

e. whether the federal securities laws were violated by Defendants' acts as alleged herein;

f. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Blue;

g. whether the Individual Defendants caused Blue to issue false and misleading financial statements during the Class Period;

h. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

i. whether the prices of Blue's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

j. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

106. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
Against All Defendants for Violations of
Section 10(b) and Rule 10b-5 Promulgated Thereunder

107. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

108. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

109. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Blue common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Blue's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

110. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Blue's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

111. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

112. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Blue's internal affairs.

113. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Blue's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Blue's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Blue's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants and were damaged thereby.

114. During the Class Period, Blue's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Blue's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired Blue common stock or would not have purchased or otherwise acquired the shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Blue's common stock was substantially less than the prices paid by Plaintiff and the other members of the Class. The market price of Blue's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

115. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

116. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

117. Plaintiff repeats and realleges each allegation contained in the foregoing paragraphs as if fully set forth herein.

118. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Blue's misstatements.

119. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Blue which had become materially false or misleading.

120. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Blue disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Blue to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Blue's common stock.

121. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Blue to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

122. By reason of the above conduct, the Individual Defendants and/or Blue are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Date: August 15, 2024

/s/ William B. Federman

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Lead Counsel for the Class

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2024. a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the Court's CM/ECF system, which will automatically notify all counsel of record.

/s/ William B. Federman
William B. Federman